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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BUNNER, BRIDGET E	
ART UNIT	**PAPER NUMBER**
1647	10

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/071,458	FEDER ET AL.	
	Examiner	Art Unit	
	Bridget E. Bunner	1647	

-- The MAILING DATE f this communication appears on the cover sheet with the correspondenc address --

Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *5-7,10-15 and 20-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,8,9 and 16-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6, 7* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election of Group I, claims 1-4, 8-9, and 16-19, drawn to an isolated nucleic acid molecule, in Paper No. 9 (18 June 2003) is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 5-7, 10-15, and 20-34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 9 (18 June 2003).

Claims 1-4, 8-9, and 16-19 are under consideration in the instant application.

Specification

1. The disclosure is objected to because of the following informalities:

2. The abstract of the disclosure is objected to because the legal term "said" is used. Applicant is reminded of the proper language and format for an abstract of the disclosure. Correction is required. See MPEP § 608.01(b).2.

2. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (See for example, pg 229, line 21). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

3. The specification is replete with references for "ATCC Deposit No. Z", which are not clear, concise, and exact.

Appropriate correction is required.

Claim Rejections - 35 USC § 101 and 35 U.S.C. § 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-4, 8-9, and 16-19 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility. Novel biological molecules lack well established utility and must undergo extensive experimentation.

Specifically, the claims are directed to an isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence at least 95.0% or 100% identical to a sequence selected from the group consisting of: (a) a polynucleotide fragment of SEQ ID NO: 1 or a polynucleotide fragment of the cDNA sequence included in ATCC Deposit No: X, (b) a polynucleotide encoding a polypeptide fragment of SEQ ID NO: 2, (c) a polynucleotide encoding a polypeptide domain of SEQ ID NO: 2, (d) a polynucleotide encoding a polypeptide epitope of SEQ ID NO: 2, (e) a polynucleotide encoding a polypeptide of SEQ ID NO: 2 or the cDNA sequence included in ATCC Deposit No: X, which is hybridizable to SEQ ID NO: 1, having potassium channel beta subunit activity, (f) a polynucleotide which is a variant of SEQ ID NO: 1, (g) a polynucleotide which is an allelic variant of SEQ ID NO: 1, (h) an isolated polynucleotide comprising nucleotides 420-1097 of SEQ ID NO: 1, (i) an isolated polynucleotide comprising nucleotides 417-1097 of SEQ ID NO: 1, (j) a polynucleotide which

represents the complimentary sequence of SEQ ID NO: 1, (k) a polynucleotide capable of hybridizing under stringent conditions to any one of the polynucleotides specified in (a)-(j). The claims also recite a recombinant vector comprising the isolated nucleic acid molecule, a recombinant host cell, and a method of making an isolated polypeptide.

The specification asserts that the human K+betaM3 polynucleotide (SEQ ID NO:1) and polypeptide (SEQ ID NO: 2) of the present invention are may share at least come biological activity with potassium channel subunits, specifically with potassium channel beta subunits (pg 25, lines 5-9). The specification also teaches that K+betaM3 has a role in immunity pathways and in the NF-κB pathway (pg 25, lines 19-21). However, the instant specification does not teach any significance or functional characteristics of the human K+betaM3 polynucleotide (SEQ ID NO: 1) or polypeptide (SEQ ID NO: 2). The specification also does not disclose any methods or working examples that indicate the polynucleotide and polypeptide of the instant invention are involved in any of the abovementioned activities. Since significant further research would be required of the skilled artisan to determine how the claimed polypeptide is involved with the above-mentioned activities, the asserted utilities are not substantial. Since the utility is not presented in mature form and significant further research is required, the utility is not substantial. The specification asserts the following as patentable utilities for the claimed putative polynucleotide (SEQ ID NO: 1):

1) to treat, diagnose, prognose, and/or prevent numerous diseases, disorders, and conditions (pg 26-35; pg 161-190)

2) as hybridization probes (pg 42, lines 26-34; pg 147-148)

3) to make a fusion protein (pg 71, lines 31-36 through pg 73)

4) for attachment to a gene chip (pg 144-145)

5) for gene therapy (pg 110-115; pg 146-147)

6) to construct a transgenic animal (pg 36, lines 25-26 through pg 37, lines 1-15)

7) in chromosome mapping (pg 142-143)

8) in tissue typing (pg 147-148)

9) to screen for therapeutic compounds or molecules which modify the activity of the polypeptide (pg 196-207)

Each of these shall addressed in turn.

1) to treat, diagnose, prognose, and/or prevent numerous diseases, disorders, and conditions. This asserted utility is not specific or substantial. The specification does not disclose disorders associated with a mutated, deleted, or translocated K+betaM3 gene (SEQ ID NO: 1). The specification does not disclose which disorders are associated with altered levels of the K+betaM3 gene. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

2) as hybridization probes. This asserted utility is not substantial or specific. Hybridization probes can be designed from any polynucleotide sequence. Further, the specification does not disclose specific cDNA, DNA, or RNA targets. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

3) to make a fusion protein. This asserted utility is not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification discloses nothing specific or substantial for the fusion protein that is produced by this method. Since this asserted

utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

4) for attachment to a gene chip. This asserted utility is not specific or substantial. Such can be performed for any polynucleotide. Further, the specification does not disclose specific nucleic acid sequences used to generate the gene chip. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5) for gene therapy. This asserted utility is not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated K+betaM3 gene of SEQ ID NO: 1. Significant further experimentation would be required of the skilled artisan to identify individuals with such a disease. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

6) to construct a transgenic animal. This asserted utility is not specific or substantial. The specification does not disclose diseases associated with a mutated, deleted, or translocated K+betaM3 gene (SEQ ID NO: 1). Significant further experimentation would be required of the skilled artisan to identify such a disease. The specification discloses nothing about whether the gene will be "knocked in" or "knocked out" or what specific tissues and cells are being targeted. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

7) in chromosome mapping. This asserted utility is not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification does not disclose a

specific DNA target. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

8) in tissue typing. This asserted utility is not substantial or specific. Such assays can be performed with any polynucleotide. Further, the specification does not disclose specific DNA sequences for use as markers for RFLP, to prepare primers, or to amplify DNA. Since this asserted utility is also not present in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

9) to screen for therapeutic compounds or molecules which modify the activity of the polypeptide. This asserted utility is not specific or substantial. Such assays can be performed with any polynucleotide. Nothing is disclosed about how the polynucleotide is affected by the compounds. Additionally, the specification discloses nothing specific or substantial for the K+betaM3 agonists, antagonists, or other agents screened in this method. Since this asserted utility is also not presented in mature form, so that it could be readily used in a real world sense, the asserted utility is not substantial.

5. Claims 1-4, 8-9, and 16-19 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

6. Furthermore, claims 1-4 and 8-9 fail to comply with the enablement requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to

make and/or use the invention. As mentioned above, the claims are directed to an isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence at least 95.0% or 100% identical to a sequence selected from the group consisting of: (a) a polynucleotide fragment of SEQ ID NO: 1 or a polynucleotide fragment of the cDNA sequence included in ATCC Deposit No: X, (b) a polynucleotide encoding a polypeptide fragment of SEQ ID NO: 2, (c) a polynucleotide encoding a polypeptide domain of SEQ ID NO: 2, (d) a polynucleotide encoding a polypeptide epitope of SEQ ID NO: 2, (e) a polynucleotide encoding a polypeptide of SEQ ID NO: 2 or the cDNA sequence included in ATCC Deposit No: X, which is hybridizable to SEQ ID NO: 1, having potassium channel beta subunit activity, (f) a polynucleotide which is a variant of SEQ ID NO: 1, (g) a polynucleotide which is an allelic variant of SEQ ID NO: 1, (h) an isolated polynucleotide comprising nucleotides 420-1097 of SEQ ID NO: 1, (i) an isolated polynucleotide comprising nucleotides 417-1097 of SEQ ID NO: 1, (j) a polynucleotide which represents the complimentary sequence of SEQ ID NO: 1, (k) a polynucleotide capable of hybridizing under stringent conditions to any one of the polynucleotides specified in (a)-(j).

The specification discloses that variants of K+betaM3 "may contain alterations in the coding regions, non-coding regions, or both. Especially preferred are polynucleotide variants containing alterations which produce silent substitutions, additions, or deletions" (pg 60, lines 13-16). The specification also teaches that known methods of protein engineering and recombinant DNA technology can generate variants to improve or alter the characteristics of the K+betaM3 polypeptides (pg 60, lines 28-30). However, the specification does not teach any variants, fragments, or allelic variants of the K+betaM3 polynucleotide or polypeptide. The specification also does not teach a nucleic acid sequence with 95% sequence identity to the

nucleotide sequence of SEQ ID NO: 1. The specification does not teach any *specific* epitopes or domains of the polypeptide encoded by SEQ ID NO: 1. Furthermore, regarding allelic variants, it is noted that such are recognized in the art as variant genes which map to the same locus on the chromosome (See Lewin, Genes II, 1985, pg 681). The specification does not disclose the chromosomal location of any of K+betaM3 gene characterized by the inventors. Additionally, the specification does not teach functional or structural characteristics of any polynucleotide variants in the context of a cell or organism.

The problem of predicting protein and DNA structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein and DNA is extremely complex. For example, while it is known that many amino acid substitutions are generally possible in any given protein the positions within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of success are limited. Certain positions in the sequence are critical to the protein's structure/function relationship, e.g. such as various sites or regions directly involved in binding, activity and in providing the correct three-dimensional spatial orientation of binding and active sites. These or other regions may also be critical determinants of antigenicity. These regions can tolerate only relatively conservative substitutions or no substitutions (see Wells, 1990, Biochemistry 29:8509-8517; Ngo et al., 1994, The Protein Folding Problem and Tertiary Structure Prediction, pp. 492-495). However, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein and DNA which are tolerant to change and the nature and extent of changes that can be made in these positions. The art recognizes that function cannot be predicted from

structure alone (Bork, 2000, Genome Research 10:398-400; Skolnick et al., 2000, Trends in Biotech. 18(1):34-39, especially p. 36 at Box 2; Doerks et al., 1998, Trends in Genetics 14:248-250; Smith et al., 1997, Nature Biotechnology 15:1222-1223; Brenner, 1999, Trends in Genetics 15:132-133; Bork et al., 1996, Trends in Genetics 12:425-427).

Due to the large quantity of experimentation necessary to determine an activity or property of the disclosed polypeptide such that it can be determined how to use the claimed polynucleotides encoding K+betaM3, to generate the infinite number of derivatives recited in the claims and possibly screen same for activity, the lack of direction/guidance presented in the specification regarding same and the lack of direction/guidance presented in the specification regarding the chromosomal locus of the K+betaM3 gene disclosed in the specification, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art establishing the unpredictability of the effects of mutation on protein structure and function and the unpredictable nature of the locus for any isolated gene, and the breadth of the claims which fail to recite particular biological activities and also embrace a broad class of structural fragments and variants and which recite any variant, allelic variant, fragment, epitope, or domain, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

7. Claims 1-4 and 8-9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to an isolated nucleic acid molecule comprising a polynucleotide having a nucleotide sequence at least 95.0% or 100% identical to a sequence selected from the group consisting of: (a) a polynucleotide fragment of SEQ ID NO: 1 or a polynucleotide fragment of the cDNA sequence included in ATCC Deposit No: X, (b) a polynucleotide encoding a polypeptide fragment of SEQ ID NO: 2, (c) a polynucleotide encoding a polypeptide domain of SEQ ID NO: 2, (d) a polynucleotide encoding a polypeptide epitope of SEQ ID NO: 2, (e) a polynucleotide encoding a polypeptide of SEQ ID NO: 2 or the cDNA sequence included in ATCC Deposit No: X, which is hybridizable to SEQ ID NO: 1, having potassium channel beta subunit activity, (f) a polynucleotide which is a variant of SEQ ID NO: 1, (g) a polynucleotide which is an allelic variant of SEQ ID NO: 1, (h) an isolated polynucleotide comprising nucleotides 420-1097 of SEQ ID NO: 1, (i) an isolated polynucleotide comprising nucleotides 417-1097 of SEQ ID NO: 1, (j) a polynucleotide which represents the complimentary sequence of SEQ ID NO: 1, (k) a polynucleotide capable of hybridizing under stringent conditions to any one of the polynucleotides specified in (a)-(j). The claims also recite a recombinant vector comprising the isolated nucleic acid molecule, a recombinant host cell, and a method of making an isolated polypeptide.

The specification teaches a human K+betaM3 polynucleotide and polypeptide (SEQ ID NO: 1 and SEQ ID NO: 2, respectively). The specification also discloses that the K+betaM3 variants of the invention may contain alterations in the coding regions, non-coding regions, or both (pg 60, lines 13-16). The specification teaches that known methods of protein engineering and recombinant DNA technology can generate variants to improve or alter the characteristics of the K+betaM3 polypeptides (pg 60, lines 28-30). However, the specification does not teach

functional or structural characteristics of the polynucleotide variants in the context of a cell or organism. The description of one K+betaM3 polynucleotide species (SEQ ID NO: 1) and one K+betaM3 polypeptide species (SEQ ID NO: 2) is not adequate written description of an entire genus of functionally equivalent polynucleotides and polypeptides which incorporate all variants, fragments, domains, and epitopes with at least 95% sequence identity to the human K+betaM3 polynucleotide comprising SEQ ID NO: 1.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed"* (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (See *Vas-Cath* at page 1116).

With the exception of the sequences referred to above, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to

lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only an isolated K+betaM3 polynucleotide that has the nucleotide sequence of SEQ ID NO:1 or a K+betaM3 polynucleotide that encodes a polypeptide having the sequence of SEQ ID NO: 2, but not the full breadth of the claim meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

8. Claims 1-4, 8-9, and 16-19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The invention appears to employ novel nucleic acid molecules. Since the nucleic acid molecules are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise readily available to the public. If the nucleic acid molecules are not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the nucleic acid molecules. The specification does not disclose a repeatable process to obtain the nucleic acid molecules and it is not apparent if the nucleic acid molecules are readily available to the public. It is noted that Applicant has deposited the nucleic acid molecules (for example, pg 17, 42, 44; Table 1 of the specification), but there is no indication in the specification as to public availability. If the deposit is made under the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an

attorney of record over his or her signature and registration number, stating that the specific nucleic acid molecules have been deposited under the Budapest Treaty and that the nucleic acid molecules will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein. If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit will be made (see 37 C.F.R. § 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Applicant's attention is directed to M.P.E.P. §2400 in general, and specifically to §2411.05, as well as to 37 C.F.R. § 1.809(d), wherein it is set forth that "the specification shall contain the accession number for the deposit, the date of the deposit, the name and address of the depository, and a description of the deposited material sufficient to specifically identify it and to permit examination. The specification should be amended to include such, however, Applicant is cautioned to avoid the entry of new matter into the specification by adding any other information.

35 USC § 112, second paragraph

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1-4, 8-9, and 16-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. The term "included in ATCC Deposit No:" in claims 1-4, 8-9, and 16-29 is a relative term which renders the claims indefinite. The term "included in ATCC Deposit No:" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear if SEQ ID NO: 1 is the cDNA sequence of ATCC Deposit No. XXX or if there is a larger DNA sequence (other than SEQ ID NO: 1) encompassed by ATCC Deposit NO: XXX.

12. The term "polynucleotide which represents the complimentary sequence" in claims 1-4, 8-9, and 16-19 is a relative term which renders the claim indefinite (see for example, claim 1(j)). The term "polynucleotide which represents the complimentary sequence " is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is not clear what DNA sequence(s) this phrase encompasses. (It is noted to Applicant that this issue could be overcome by amending the claims to recite "a polynucleotide which is the complementary sequence...".).

13. Stringency is relative, and the art does not recognize a single set of conditions as stringent. The specification also does not provide an unambiguous definition for the term. In the

absence of a recitation of clear hybridization conditions (e.g., "hybridizes at wash conditions consisting of **A** X SSC and **B** % SDS at **C**°C"), claims 1-4 and 8-9 fail to define the metes and bounds of the varying structures of polynucleotides recited in the claimed methods.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bridget E. Bunner whose telephone number is (703) 305-7148. The examiner can normally be reached on 8:30-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 872-9305.

Elizabeth C. Kemmerer

BEB
Art Unit 1647
03 September 2003

ELIZABETH KEMMERER
PRIMARY EXAMINER